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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,738	09/27/2001	Timothy J. O'Brien	022438.43865	3856

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EXAMINER	
NICKOL, GARY B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/965,738	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Gary B. Nickol Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.60

Re: O'Brien *et al.*

DETAILED ACTION

Upon review and reconsideration, the restriction requirement mailed 06-10-2003 is withdrawn.

A new restriction requirement is set forth below:

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 20-26, drawn to ONE isolated nucleic acid, a vector thereof, and cultured cell, classified in class 536, subclass 23.1; class 435, subclasses 69.1, 320.1, 325.

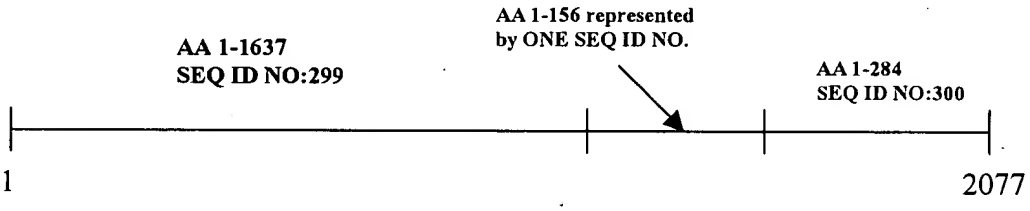
(Upon election of Group I above, Applicant must further elect ONE nucleic acid from those listed in Claim 20, part a, and ONE corresponding encoded polypeptide from those listed in Claim 21, part a, as each sequence represents a separate invention, not a species. Additionally, Claim 26 will only be examined to the extent it reads on the elected sequence(s).)

II. Claims 14-19, 27, 30-33 drawn to ONE purified polypeptide, classified in class 530, subclass 350; class 424, subclass 184.1.

(Upon election of Group II above, Applicant must further elect ONE polypeptide sequence from those listed in Claim 27, part a, as each sequence represents a separate invention, not a species. Claims 14-19 will only be examined to the extent they read on the elected sequence.)

III. Claims 1-12, drawn to ONE CA125 molecule comprising an extracellular domain of SEQ ID NO:299, ONE repeat domain, and ONE cytoplasmic domain comprising SEQ ID NO:300, classified in class 530, subclass 350.

Upon election of Group III, applicants must further elect ONE multiple repeat domain corresponding to ONE linear sequence identifier comprising amino acids 1-156 of domains 1-5. For example, upon election, of group III, a search and examination of a 2077 AA polypeptide will take place as set forth below:



CA125

IV. Claim 13, drawn to a CA125 molecule comprising SEQ ID NO:162, classified in class 530, subclass 350.

V. Claims 28-29 drawn to a purified antibody that binds to ONE polypeptide, classified in class 530, subclass 387.1.

(Upon election of Group V above, Applicant must further elect ONE polypeptide sequence from those listed in Claim 28, part a, as each sequence represents a separate invention, not a species.)

VI. Claim 34, drawn to ONE antisense molecule, classified in class 800, subclass 286.

(Upon election of Group VI above, Applicant must further elect ONE nucleic acid from those listed in Claim 20, part a, as each sequence represents a separate invention, not a species.)

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I is related to the protein of group II by virtue of the fact that the DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include multiple distinct sequences inclusive of various complements and fragments. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above: furthermore, a search of the nucleic acid molecules of Group I would require an oligonucleotide search, which is not likely to result in relevant art with respect

to the polypeptide of group II. As such, it would be burdensome to search the inventions of Groups I and II.

The polypeptides of Group II and the antibodies of Group V are patentably distinct for the following reasons:

While the inventions of both Group II and Group V are polypeptides, in this instance the polypeptides of Group II represent various polypeptides of the CA125 gene, whereas the polypeptide of Group V encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementary determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group II and the antibodies of Group V are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group V is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptides of group II encompass large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group V is defined in terms of its binding specificity to a small structure within the sequences encompassed by the claimed peptides. Furthermore, searching the inventions of Group II and Group V would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a

search is not required to identify the antibodies of Group V. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptides of Group II and the antibody of Group V are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotides of Group I and VI and the antibody of Group V are patentably distinct for the following reasons:

The antibody of Group V includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibody of Group V which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I (or VI) will not encode an antibody of Group V, and the antibody of Group V cannot be encoded by a polynucleotide of Group I (or VI). Therefore, the antibody and polynucleotides are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I (or VI) and Group V would impose a serious search burden since a search of the polynucleotides of Group I would not be used to determine the patentability of any antibody of Group V, and vice-versa.

Groups III and IV are unrelated to Groups I-II, and V-VI in that Groups III and IV as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions. Groups III and IV define over 130 distinct polypeptides that are chemically distinct molecules. A search for all such peptides would be unduly burdensome. Currently, there are approximately eight different databases that accompany the results of a search of one discrete amino acid or nucleotide sequence and each result set from a particular database must be carefully considered. Hence, the search of all such different polypeptides, and different polypeptide segments in the databases would require extensive searching and review. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER